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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,417

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Shinichi Sakane

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,417	Applicant(s) SAKANE ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/30/10; 10/29/10</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/5/10 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 2, 4 – 8 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,291,054 to Thomas et al. in view of U.S. Patent Application Publication No. 2002/0082524 to Anderson et al. and U.S. Patent Application Publication No. 2002/0172829 to Mori et al.

In regard to claims 1, 2, 4 – 8 and 11 Thomas et al. disclose a fluororesin coating layer formed on a metal surface (Col. 9, lines 10 - 14) wherein particulate matter is present in the fluororesin coating layer (Col. 2, lines 67 - Col. 3, line 2), and the fluororesin coating and the particulate matter are baked as a single unit (Col. 8, lines 61 – 63) to at least a melting point of the fluororesin (Col. 8, lines 63 – 65) in that the melting point of PTFE is about 651°F (Plastics International); and wherein the fluororesin coating layer is an outermost layer that covers the

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particulate matter and at least some of the particulate matter is formed in surface protrusion-shaped smooth projections (Col. 3, lines 2 – 6, 22 – 27). Because the projections provide less surface area for contact with another object, the frictional resistance is reduced. Thomas et al. disclose a primer layer being further formed within the fluororesin coating layer; wherein particulate matter is present in at least one layer selected from the primer layer and the fluororesin coating layer; and wherein the fluororesin coating layer of the outermost layer covers the particulate matter and at least some of the particulate matter is formed in surface protrusion-shaped projections (Col. 4, lines 31 – 40). The thickness of the fluororesin coating layer is at least 1 μm and not more than 50 μm (Col. 3, line 36). The average height of the projections is at least 0.1 μm and not more than 20 μm (Col. 2, line 33). The fluororesin coating layer surface has a mixture of flat portions and numerous protrusion-shaped projections (Figure 1). The density of the protrusion-shaped projections is at least and average of 1 per 0.01 mm^2 (Col. 4, lines 60 – 64). Thomas et al. disclose the particulate matter being present in the primer layer (Col. 4, lines 31 – 40), and the particulate matter is fluororesin or a heat-resistant substance having a higher melting point than the fluororesin coating layer (Col. 7, lines 32 – 36; Col. 8, lines 37 – 41). The average particle diameter of the particulate matter is at least the film thickness of the primer layer, and the average particle diameter is in a range of 0.5 to 30 μm (Col. 3, lines 14 – 16; Col. 4, lines 43 – 41). Thomas et al. disclose the substrate being any material such as metal and stainless steel (Col. 9, lines 10 – 14), but fails to disclose the substrate being a metal guide wire having a uniform thickness or a tapered tip. Anderson et al. disclose a guide wire formed of metal having a uniform thickness or a tapered tip (Figure 4) having any fluoropolymer coating [0019]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the substrate disclosed by Thomas et al. to be a metal guide wire as taught by Anderson et al. in order to produce a guide wire having a durable, non-stick coating with superior abrasion

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resistance (Col. 2, lines 8 - 9). Thomas et al. in view of Anderson et al. disclose the fluororesin coating layer including at least one of selected from the group consisting of polytetrafluoroethylene (PTFE), tetrafluoroethylene- perfluoroalkylvinyl ether copolymer (PFA), polychlorotrifluoroethylene (PCTFE), polyvinylidene fluoride (PVDF), polyvinyl fluoride (PVF), tetrafluoroethylene-hexafluoropropylene copolymer (FEP), and tetrafluoroethylene-ethylene copolymer (PETFE) (Col. 4, line 66 – Col. 5, line 19) and the particulate matter including a variety of materials (Col. 8, lines 37 – 41). However, Thomas et al. in view of Anderson et al. fail to disclose the particulate matter including a fluororesin. Mori et al. disclose a coating layer including particulate matter, wherein the particulate matter is a fluororesin selected from the group consisting of polytetrafluoroethylene (PTFE), tetrafluoroethylene- perfluoroalkylvinyl ether copolymer (PFA), polychlorotrifluoroethylene (PCTFE), polyvinylidene fluoride (PVDF), polyvinyl fluoride (PVF), tetrafluoroethylene-hexafluoropropylene copolymer (FEP), and tetrafluoroethylene-ethylene copolymer (PETFE) [0051][0055]. The claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of using a fluororesin particulate as taught by Mori et al. for the predictable result of forming surface protrusions. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fluororesin particulate as taught by Mori et al. to allow for continued friction reduction in the event that a particle protrudes out of the coating. The limitation related to the fluororesin coating layer and the particulate matter of fluororesin being baked by heating to melt into a single unit is a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by these steps. In the present case, the structure is particulate matter of

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fluororesin within a coating layer. This is disclosed by the combination of Thomas et al. in view of Anderson et al. and Mori et al.

Response to Arguments

4. Applicant's arguments filed 10/5/10 have been fully considered but they are not persuasive. Applicant asserts that Thomas et al. teach that fluororesin particles are incapable of deflecting abrasive forces from the coating and thus teaches away from using fluororesin particles. However, the Examiner disagrees. Thomas et al. state that the particulate matter may include a variety of materials (Col. 8, lines 37 – 41). Thomas et al. does not state that fluororesin particles should not be used. Mori et al. disclose a coating layer including particulate matter, wherein the particulate matter is a fluororesin. The claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of using a fluororesin particulate as taught by Mori et al. for the predictable result of forming surface protrusions. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a fluororesin particulate as taught by Mori et al. to allow for continued friction reduction in the event that a particle protrudes out of the coating. Applicant improperly states that the previous rejection erroneously associated the property of friction reduction to particles protruding out of the coating. This is not what the Examiner stated. Thomas et al. is clear that it is not desirable for particles to protrude from the coating (See 17 Figure 1). However, because the projections (18, 19, 20) of Thomas et al. rise above the surface of the coating and deflect abrasion force away from the coating, they also provide less surface area for the abrasive force to act against the coating, thus reducing a frictional resistance between the coating and a force against the coating. Prather (U.S. Patent No. 5,404,887) supports this rationale. Prather teaches

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utilizing projections on a surface to minimize the surface area between two components and thus reduce friction. In the case with a ceramic particle rising above the surface, friction would be greatly increased. However, if a fluoro resin particle were to rise above the surface of the coating, the fluoro resin particle would have a lower level of friction than that of a ceramic particle. In regard to "release". It is noted that with the increase of surface area by forming the protrusions, that when used with food, which is capable of fitting between the protrusions, the increase in surface area would allow more friction and thus worse release between the food and the coating. However, this would not be the case when a guidewire is positioned within in a catheter. The protrusions would keep the catheter from coming into contact with the entirety of the coating (See Prather). The limitation related to the fluoro resin coating layer and the particulate matter of fluoro resin being baked by heating to melt into a single unit is a product by process limitation. As set forth in MPEP 2113, product by process claims are NOT limited to the manipulations of the recited steps, only to the structure implied by these steps. In the present case, the structure is particulate matter of fluoro resin within a coating layer forming projections. This is disclosed by the combination of Thomas et al. in view of Anderson et al. and Mori et al. Applicant asserts that Thomas et al. specifically teach that the ceramic particles are structurally separate from the coating layers and cannot be considered as being melted into a single unit. However, the Examiner disagrees. The claims require fluoro resin layer and the particulate matter to be compatible and melt into a single unit. The fluoro resin layer and the particles disclosed by Thomas et al. are compatible with one another in that they are not incompatible. The coating disclosed by Thomas et al. does melt into a single unit. The Examiner offers the following illustration to clarify the interpretation of "a single unit": a jello mold having fruit dispersed throughout is "a single unit". The claims do not require

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the fluororesin layer and the particulate matter to be mixed/fused so the particulate matter blends with the layer so that they are not structurally separate.

5. The declaration under 37 CFR 1.132 filed 10/5/05 is insufficient to overcome the rejection of the claims as set forth in the last Office action. Evidence pertaining to secondary considerations must be taken into account whenever present; however, it does not necessarily control the obviousness conclusion. See, e.g., *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1372, 82 USPQ2d 1321, 1339 (Fed. Cir. 2007) (“the record establish [ed] such a strong case of obviousness” that allegedly unexpectedly superior results were ultimately insufficient to overcome obviousness conclusion); *Leapfrog Enterprises Inc. v. Fisher-Price Inc.*, 485 F.3d 1157, 1162, 82 USPQ2d 1687, 1692 (Fed. Cir. 2007) (“given the strength of the prima facie obviousness showing, the evidence on secondary considerations was inadequate to overcome a final conclusion” of obviousness); and *Newell Cos., Inc. v. Kenney Mfg. Co.*, 864 F.2d 757, 768, 9 USPQ2d 1417, 1426 (Fed. Cir. 1988). In regard to the secondary considerations directed to commercial success, Applicant has failed to establish a nexus between the rebuttal evidence and the claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm. Applicant is invited to contact the Examiner at the number above to discuss the present Office Action.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736